REMARKS

Claims 1-62 and 81 are pending in this application. Claims 11 and 41 have been canceled without prejudice. Claims 1, 31 and 81 were amended without prejudice and without conceding to the Examiner's characterizations. Each of the pending claims has been rejected, and Applicant traverses each rejection as follows.

35 U.S.C. § 112, first paragraph

WRITTEN DESCRIPTION

The Examiner has rejected claims 1-12, 14-42, 44-62 and 81 under 35 U.S.C. § 112, first paragraph, (a written description rejection). "Applicant's claimed expression represents only an invitation to experiment regarding possible compounds suitable as sulfur derivatives, which can be used in the compositions for absorbing irritants in the skin and delivering sulfur." Applicant traverses this rejection for at least the following reasons.

First, claims 61 and 62 do not use the term "sulfur derivative," and therefore the rejection is inapplicable to these claims. Second, Applicant has amended claim 1 (and the other pending claims are dependent on claim 1) to enumerate sulfur derivatives, as they are described in the specification. Therefore, the sulfur derivatives satisfy written description requirements and Applicant respectfully requests that this rejection be withdrawn.

ENABLEMENT

Claims 1-12, 14-42, 44-62 and 81 were rejected under 35 U.S.C. § 112, first paragraph as being not enabled. Applicant traverses this rejection for at least the following reasons.

The Examiner alleges that "the specification, while being enabled for using the claimed method using the compositions which has sulfur and sodium sulfacetamide, does not

reasonably provide enablement for claimed method using sulfur and sulfur derivatives. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims." The Examiner then sets forth eight (8) factors for evaluating whether "a disclosure would require undue experimentation." Applicant traverses this rejection for at least the following reasons.

Under "state of the prior art," the Examiner asserts that sulfur at concentrations over 6% is toxic. The Examiner's contention that the use of more than 6% sulfur is toxic is simply wrong and furthermore, one of ordinary skill in the art would know and understand the invention to cover the amount of sulfur which is beneficial and non-toxic. A noted expert in dermatology, Professor Ronald Marks, has set forth a declaration to this effect ("Marks' Declaration" attached hereto as Exhibit 1). Marks is a celebrated author, researcher and professor in dermatology (Marks Declaration, ¶¶ 1-5). He is also a clinical dermatologist, familiar with skin disorders and their treatments (Marks Declaration, ¶ 6). He notes that sulphur is used in topical medications, which he prescribes (Marks Declaration, ¶¶ 8 and 10). Marks reviewed the Maibach article cited by the Examiner and notes that Maibach used precipitated sulfur (6%) in petrolatum and "never [saw] an example of systemic toxicity or fatality." (Marks Declaration, ¶ 11). According to Marks, "'Dermatology,' (Braun-Falco, O., et al., p. 1156 Springer-Verlag 1991) describes pastes and ointments containing 2,10, and 20% sulphur," and another article describes the use of 10% sulphur in topical application . (Marks Declaration, ¶¶ 12-13). Several textbooks and articles recommend the topical use of sulphur as "safe and effective," including the Federal Register, which approves the use of 3-10% sulphur and none of these references mention "adverse systemic effects from its use." (Marks Declaration, ¶¶ 14-18, 21, and 23). Marks noted that the only literature he found regarding sulphur toxicity was due to ingestion of sulphur by animals in large amounts, NOT topical application. (Marks Declaration

¶¶ 19-20). According to Marks, "One of ordinary skill in the art would have no reason to believe that a 10% or less topical preparation of sulphur would cause systemic toxicity. Rather, one of ordinary skill in the art would have reason to believe that a 10% or less topical sulphur preparation is safe and effective in light of the fact that the use of 3-10% sulphur in topical over the counter drugs has been approved by the Food and Drug Administration," and has been cited approvingly in other literature (Marks Declaration, ¶¶ 24 and 26). "One of ordinary skill in the art [would know and understand from the specification of this application] that sulphur and sulphur derivatives can be and are used in the treatment of dermatological conditions up to about 10%." (Marks Declaration ¶ 26). Products having more than 6% sulfur have been used for many years, and have been specifically approved by the U.S. Food and Drug Administration ("FDA"). The FDA published acceptable concentration ranges of sulfur in topical drug products as "3 to 10 percent." See 21 C.F.R. §333.310 from 50 FR 2172, a copy of which is attached as Exhibit A to Marks Declaration.

If the Examiner is prepared to dispute Professor Marks' sworn testimony, the accuracy of the FDA Monograph, or the well-established practices of practitioners in this field, then Applicant requests an affidavit by the Examiner under 37 C.F.R. § 1.104(d)(2). Absent evidence by the Examiner, it must be accepted that one of ordinary skill in the art would know that these are acceptable ranges without undue experimentation, and that the requirements of 35 U.S.C. §112, ¶ 1 are fulfilled.

The Examiner then asserts that "the specification fails to describe the nature [of] R for the organic sulfide and the nature of R for the sulfites and inorganic sulfites. None of the sulfur derivatives are art-recognized equivalents." As noted in the argument above, "sulfur derivatives" has been amended to "organic sulfides, inorganic sulfides, organic mercaptans, inorganic mercaptans, cationic sulfur compounds, H_2S, sulfuric acid, bisulfides, sulfur dioxide,

thiols [or] sodium sulfacetamide". It is noted that the R group is not limited because it is sulfur (not the R group) in sulfur derivatives that produces the desired effects of the sulfur derivatives in this method. Sulfur derivatives in the pending claims as amended are definite.

Finally, the Examiner asserts that "[d]ue to the divergent nature of the sulfur derivatives, one of ordinary skill in the art cannot extrapolate the test results to all the sulfur derivatives, and the practice of the full scope of the invention would require undue experimentation." Under MPEP § 2164.04, the examiner must "specifically identify what information is missing and why one of skill in the art could not supply the information without undue experimentation." The Examiner provides no support for the statement "none of the sulfur compounds are art-recognized equivalents." Further, all of the pending claims have been amended to enumerate the sulfur derivatives, and therefore there is no experimentation required at all. Additionally, since the Examiner has not shown that one of skill in the art would not know how to make or use the invention without undue experimentation, the Examiner did not meet the burden under MPEP 2164.04. Again, the Examiner is requested to make an affidavit under 37 C.F.R. § 1.104(d)(2) if the rejection is maintained. For all of the foregoing reasons, this rejection should be removed.

35 U.S.C. § 102

Lin

The Examiner has rejected claims 1, 11-15, 30-31, 33-36, 41-45, 56, 60 and 81 under 35 U.S.C. § 102(b) as being anticipated by Lin. Applicant traverses this rejection for at least the following reasons.

According to the Examiner, "Table IV discloses topical preparations that contain sulfur and sulfacetamide...Sulfacet-R acne lotion ...reads on the claims that recite sulfur and sulfur derivatives. The lotion reads on the sorption bas[e]." However, Applicant has amended

the independent claims 1, 31, and 81 (and therefore their dependent claims) to exclude attapulgite as a high sorption base.

Attapulgite is present in the Sulfacet-R acne lotion. The present invention in one embodiment was compared to Sulfacet-R lotion in order to display one of the unexpected benefits of the invention, i.e. the present invention does not exhibit sulfur malodor unlike the prior art (e.g. Sulfacet-R lotion). Attached as Exhibit 2 is an affidavit by Eugene H. Gans ("Gans Affidavit), an expert in the art and an inventor. For 35 days, the present invention (designated Plexion SCT), Sulfacet-R Lotion and Sulfacet-R Tint-Free Lotion were maintained at 25C. (See Gans Affidavit ¶ IIA.) A controlled odor evaluation was performed and the observed odors were recorded at Day 1, 6, 13, 22 and 35 days. (Gans Affidavit ¶ IIA)

The present invention did not emit sulfur odor for the entire 35 days. However, Sulfacet-R and Sulfacet-R Tint Free both emitted sulfur and chemical odors. (Gans Affidavit III). As noted by Dr. Gans, "[t]he present invention unexpectedly and surprisingly minimizes the malodors of sulfur and sulfur derivative compositions as compared to the prior art compositions." (Gans Affidavit IV A)

Therefore, Lin does not read on the pending claims and the present invention is patentably distinct from the prior art. Applicant respectfully requests that this rejection be removed.

35 U.S.C. § 103

Lin and '301 Patent and Skin Care and Cosmetics Dictionary ("Skin Care Dictionary")

The Examiner has rejected claims 1-60 and 81 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Lin and '301 Patent and Skin Care Dictionary. According

to the Examiner, "both the article and the patent teach...treating acne using sulfur and sulfur derivatives..." Applicant traverses this rejection for at least the following reasons.

The '301 patent does not teach using both sulfur and sulfur derivatives in one composition. Sulfur is only used by itself in the Comparative Experiment A, and never in the compositions with a sulfur derivative in the '301 patent. Further, as Applicant noted above, Lin (referred to as the article by the Examiner) only teaches one composition which uses both sulfur and a sulfur derivative on acne, and as noted above, this composition is malodorous, unlike the present invention. See Gans Affidavit III. One of ordinary skill in the art would not find it obvious to use a malodorous composition of sulfur and a sulfur derivative in connection with the '301 patent because the '301 patent was attempting to deodorize compositions. (See Col. 1, Line 14) In fact, Lin's composition actually teaches away from combination with the '301 patent because Lin's composition was malodorous. Additionally, both the '301 patent and Lin require attapulgite, and the present invention's high sorption base is substantially free of attapulgite.

The Examiner also cites Skin Care and Cosmetic Ingredients Dictionary as support for, "[g]ums are used for the known property as thickeners or gelling agents and one of ordinary skill in the art would be motivated to use gums expecting that the formulation would be viscous." However, gum is used in the present invention as a high sorption base. The Examiner has introduced no evidence that thickening or gelling agents would be obvious choices to absorb irritants from the skin, and the prima facie case for obviousness has not been met by the Examiner. One of ordinary skill in the art would not find it obvious to use gums as high sorption bases. Therefore, Applicant respectfully requests removal of this rejection.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment, to Deposit Account #18-0586. This authorization also hereby includes a request

for any extensions of time of the appropriate length required upon the filing of any reply during the entire prosecution of this application.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/022,482 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 703 872 9306 on the date shown below.

Maryellen Feehery

March 16, 2004
Date of Facsimile Transmission

Respectfully submitted,

Maryellen Feehery
Registration No.: 44,677
William J. McNichol, Jr.
Registration No. 31,179
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
(215) 241-7988

Attorneys for Applicant